There is a very cooperative, very, frankly, exciting group meeting together right now, probably as we speak, trying to come up with a comprehensive solution that involves the tribes, the farmers, environmentalists, power companies, everybody involved in this basin.

This administration, this Congress, put forth $10 million to screen the ''A'' canal so that sucker larvae could come back into Klamath Lake; 100,000 acre feet of water was put in streams away from agriculture, and a water bank to put more water into this system. We have passed the authority and funding to remove Chiloquin Dam to improve fish passage, the upper end that deals with sucker recovery.

In the farm bill, $50 million, the only earmark for EQUIP funding, was carved out by this Congress to help in terms of both irrigation efficiency and conservation programs and partnerships between farmers to put more water into the system. There is an enormous effort under way in this basin by this administration, by this administration, and in a bipartisan way by this Congress. We recognize more work needs to be done.

Mr. RAHALL. Mr. Speaker, this concludes debate on our side of the aisle. Again, commending our chairman, Mr. POMBO, wishing him the best on whatever avenue he pursues in the future. I know that he will be spending a great deal of time on the ranch with his lovely wife, Annette. I wish him Godspeed there.

I thank Mr. GILCHREST for his work on this legislation, those that have spoken on it for the help they have been, especially, as I started out my remarks, I thank Senator STEVENS and Senator INOUYE who truly extended the olive branch that broke the logjam on this legislation.

As Mr. ALLEN has already done, I also want to recognize our committee Democratic staff who helped make this bill possible. Chief among them is Lori Sonken, as well as Jeff Petrich and Charlotte Stevenson.

I thank Mr. POMBO's staff as well. His staff has put in numerous hours on this over a long, long period of time. Without their work we would not be here today celebrating the passage of this legislation.

Mr. Speaker, I yield back the balance of my time.

Mr. GILCHREST. I want to thank Mr. RAHALL and his staff and the Members on that side of the aisle, and Mr. POMBO for his effort, Mr. YOUNG, and Mr. Jim Saxton, and certainly the staff behind me for all their work.

This is not a perfect bill. There is no utopia in the legislative process. Through consensus and dialogue, we have tried to integrate the ideas of the Members, and we feel very strongly that we have come up with a bill that will improve, sustain and restore the ecology of the Nation's oceans.

I urge my colleagues for an ''aye'' vote on this legislation.

Mr. REICHERT. Mr. Speaker, I rise today in support of H.R. 5946, a bill to reauthorize the Magnuson-Stevens Fishery Conservation and Management Act. This bill will improve the management of our nation's fishery resources, and help ensure that we have a sustainable supply of seafood for Americans. Importantly, the new bill would permit regional fishery councils to implement market-based management programs for fisheries that will improve the economics of fishing and enhance the safety of our fishing fleets.

I am also pleased that the new legislation would not disrupt the ongoing efforts by the Pacific Fishery Management Council to improve the management of its groundfish fisheries. The Pacific Council is working diligently to develop a rationalization program for its groundfish fisheries. This process has been underway for more than 3 years, and is nearing completion. While the bill requires the Pacific Council to implement an appropriate groundfish management program within 24 months from the date of enactment, and to meet other requirements in the new law, it does not require the Pacific Council to begin anew in developing that program.

I would like to thank Chairman POMBO and Ranking Member RAHALL for their efforts on this bill, and for their willingness to work with us on issues of importance to our Pacific Northwest fisheries.

Mr. GILCHREST. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Maryland (Mr. GILCHREST) that the House suspend the rules and concur in the Senate amendment to the bill, H.R. 5946.

The question was taken; and (two-thirds of those voting having responded in the affirmative) the rules were suspended and the Senate amendment was concurred in.

A motion to reconsider was laid on the table.

FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed without amendment a bill and a joint resolution of the House of the following titles:

H.R. 4709. An act to amend title 18, United States Code, to strengthen protections for law enforcement officers and the public by providing criminal penalties for the fraudulent acquisition or unauthorized disclosure of phone records.

H.J. Res. 102. Joint resolution making further continuing appropriations for the fiscal year 2007, and for other purposes.

The message also announced that the Senate has passed with an amendment in which the concurrence of the House is requested, bills of the House of the following titles:

H.R. 798. An act to provide for a research program for remediation of closed methamphetamine production laboratories, and for other purposes.

H.R. 6164. An act to amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

NATIONAL INSTITUTES OF HEALTH REFORM ACT OF 2006

Mr. BARTON of Texas. Mr. Speaker, I move to suspend the rules and concur in the Senate amendment to the bill (H.R. 6164) to amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

The Clerk read as follows:

Senate amendment:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Institutes of Health Reform Act of 2006''.

TITLE I—NIH REFORM

SEC. 101. ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—Section 401 of the Public Health Service Act (42 U.S.C. 281) is amended to read as follows:

''SEC. 401. ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

''(a) RELATION TO PUBLIC HEALTH SERVICE.—The National Institutes of Health is an agency of the Service.

''(b) NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—The following agencies of the National Institutes of Health are national research institutes or national centers:

''(1) The National Cancer Institute.

''(2) The National Heart, Lung, and Blood Institute.

''(3) The National Institute of Diabetes and Digestive and Kidney Diseases.

''(4) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

''(5) The National Institute on Aging.

''(6) The National Institute of Allergy and Infectious Diseases.

''(7) The National Institute of Child Health and Human Development.

''(8) The National Institute of Dental and Craniofacial Research.

''(9) The National Eye Institute.

''(10) The National Institute of Neurological Disorders and Stroke.

''(11) The National Institute on Deafness and Other Communication Disorders.

''(12) The National Institute on Alcohol Abuse and Alcoholism.

''(13) The National Institute on Drug Abuse.

''(14) The National Institute of Mental Health.

''(15) The National Institute of General Medical Sciences.

''(16) The National Institute of Environmental Health Sciences.

''(17) The National Institute of Nursing Research.

''(18) The National Institute of Biomedical Imaging and Bioengineering.

''(19) The National Human Genome Research Institute.

''(20) The National Library of Medicine.

''(21) The National Center for Research Resources.

''(22) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

''(23) The National Center for Complementary and Alternative Medicine.

''(24) The National Center on Minority Health and Health Disparities.

''(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

''(c) DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES.—

''(1) IN GENERAL.—Within the Office of the Director of the National Institutes of Health, there

shall be a Division of Program Coordination, Planning, and Strategic Initiatives (referred to in this subsection as the 'Division').

''(2) OFFICES WITHIN DIVISION.—

''(A) OFFICES.—The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, the Office of Rare Diseases, and any other office located within the Office of the Director of NIH as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006. In addition to such offices, the Director of NIH may establish within the Division such additional offices or other administrative units as the Director determines to be appropriate.

''(B) AUTHORITIES.—Each office in the Division—

''(i) shall continue to carry out the authorities that were in effect for the office before the date of enactment referred to in subparagraph (A); and

''(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 402(b)(7).

''(d) ORGANIZATION.—

''(1) NUMBER OF INSTITUTES AND CENTERS.—In the National Institutes of Health, the number of national research institutes and national centers may not exceed a total of 27, including any such institutes or centers established under authority of paragraph (2) or under authority of this title as in effect on the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.''.

(b) ADDITIONAL PROVISIONS REGARDING ORGANIZATION.—Section 401 of the Public Health Service Act, as added by subsection (a) of this section, is amended—

(1) in subsection (d), by adding at the end the following:

''(3) REORGANIZATION OF OFFICE OF DIRECTOR.—Notwithstanding subsection (c), the Director of NIH may, after a series of public hearings, and with the approval of the Secretary, reorganize the offices within the Office of the Director, including the addition, removal, or transfer of functions of such offices, and the establishment or termination of such offices, if the Director determines that the overall management and operation of programs and activities conducted or supported by such offices would be more efficiently carried out under such a reorganization.

''(4) INTERNAL REORGANIZATION OF INSTITUTES AND CENTERS.—Notwithstanding any conflicting provisions of this title, the director of a national research institute or a national center may, after a series of public hearings and with the approval of the Director of NIH, reorganize the divisions, centers, or other administrative units within such institute or center, including the addition, removal, or transfer of functions of such units, and the establishment or termination of such units, if the director of such institute or center determines that the overall management and operation of programs and activities conducted or supported by such divisions, centers, or other units would be more efficiently carried out under such a reorganization.''; and

(2) by adding after subsection (d) the following:

''(e) SCIENTIFIC MANAGEMENT REVIEW BOARD FOR PERIODIC ORGANIZATIONAL REVIEWS.—

''(1) IN GENERAL.—Not later than 60 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the 'Board').

''(2) DUTIES.—

''(A) REPORTS ON ORGANIZATIONAL ISSUES.—The Board shall provide advice to the appropriate officials under subsection (d) regarding the use of the authorities established in paragraphs (2), (3), and (4) of such subsection to reorganize the National Institutes of Health (referred to in this subsection as 'organizational authorities'). Not less frequently than once each 7 years, the Board shall—

''(i) determine whether and to what extent the organizational authorities should be used; and

''(ii) issue a report providing the recommendations of the Board regarding the use of the authorities and the reasons underlying the recommendations.

''(B) CERTAIN RESPONSIBILITIES REGARDING REPORTS.—The activities of the Board with respect to a report under subparagraph (A) shall include the following:

''(i) Reviewing the research portfolio of the National Institutes of Health (referred to in this subsection as 'NIH') in order to determine the progress and effectiveness and value of the portfolio and the allocation among the portfolio activities of the resources of NIH.

''(ii) Determining pending scientific opportunities, and public health needs, with respect to research within the jurisdiction of NIH.

''(iii) For any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation in such report—

''(I) analyzing the budgetary and operational consequences of the proposed changes;

''(II) taking into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research institutes and centers that have been in existence for more than two decades;

''(III) estimating the level of resources needed to implement the proposed changes;

''(IV) assuming the proposed changes will be made and making a recommendation for the allocation of the resources of NIH among the national research institutes and national centers; and

''(V) analyzing the consequences for the progress of research in the areas affected by the proposed changes.

''(C) CONSULTATION.—In carrying out subparagraph (A), the Board shall consult with—

''(i) the heads of national research institutes and national centers whose directors are not members of the Board;

''(ii) other scientific leaders who are officers or employees of NIH and are not members of the Board;

''(iii) advisory councils of the national research institutes and national centers;

''(iv) organizations representing the scientific community; and

''(v) organizations representing patients.

''(3) COMPOSITION OF BOARD.—The Board shall consist of the Director of NIH, who shall be a permanent nonvoting member on an ex officio basis, and an odd number of additional members, not to exceed 21, all of whom shall be voting members. The voting members of the Board shall be the following:

''(A) Not fewer than 9 officials who are directors of national research institutes or national centers. The Secretary shall designate such officials for membership and shall ensure that the group of officials so designated includes directors of—

''(i) national research institutes whose budgets are substantial relative to a majority of the other institutes;

''(ii) national research institutes whose budgets are small relative to a majority of the other institutes;

''(iii) national research institutes that have been in existence for a substantial period of time without significant organizational change under subsection (d);

''(iv) as applicable, national research institutes that have undergone significant organization changes under such subsection, or that have been established under such subsection, other than national research institutes for which such changes have been in place for a substantial period of time; and

''(v) national centers.

''(B) Members appointed by the Secretary from among individuals who are not officers or employees of the United States. Such members shall include—

''(i) individuals representing the interests of public or private institutions of higher education that have historically received funds from NIH to conduct research; and

''(ii) individuals representing the interests of private entities that have received funds from NIH to conduct research or that have broad expertise regarding how the National Institutes of Health functions, exclusive of private entities to which clause (i) applies.

''(4) CHAIR.—The Chair of the Board shall be selected by the Secretary from among the members of the Board appointed under paragraph (3)(B). The term of office of the Chair shall be 2 years.

''(5) MEETINGS.—

''(A) IN GENERAL.—The Board shall meet at the call of the Chair or upon the request of the Director of NIH, but not fewer than 5 times with respect to issuing any particular report under paragraph (2)(A). The location of the meetings of the Board is subject to the approval of the Director of NIH.

''(B) PARTICULAR FORUMS.—Of the meetings held under subparagraph (A) with respect to a report under paragraph (2)(A)—

''(i) one or more shall be directed toward the scientific community to address scientific needs and opportunities related to proposals for organizational changes under subsection (d), or as the case may be, related to a proposal that no such changes be made; and

''(ii) one or more shall be directed toward consumer organizations to address the needs and opportunities of patients and their families with respect to proposals referred to in clause (i).

''(C) AVAILABILITY OF INFORMATION FROM FORUMS.—For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

''(6) COMPENSATION; TERM OF OFFICE.—The provisions of subsections (b)(4) and (c) of section 406 apply with respect to the Board to the same extent and in the same manner as such provisions apply with respect to an advisory council referred to in such subsections, except that the reference in such subsection (c) to 4 years regarding the term of an appointed member is deemed to be a reference to 5 years.

''(7) REPORTS.—

''(A) RECOMMENDATIONS FOR CHANGES.—Each report under paragraph (2)(A) shall be submitted to—

''(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives;

''(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate;

''(iii) the Secretary; and

''(iv) officials with organizational authorities, other than any such official who served as a member of the Board with respect to the report involved.

''(B) AVAILABILITY TO PUBLIC.—The Director of NIH shall post each report under paragraph (2) on the Internet site of the National Institutes of Health.

''(C) REPORT ON BOARD ACTIVITIES.—Not later than 18 months after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Board shall submit to the committees specified in subparagraph (A) a report describing the activities of the Board.

''(f) ORGANIZATIONAL CHANGES PER RECOMMENDATION OF SCIENTIFIC MANAGEMENT REVIEW BOARD.—

''(1) IN GENERAL.—With respect to an official who has organizational authorities within the

meaning of subsection (e)(2)(A), if a recommendation to the official for an organizational change is made in a report under such subsection, the official shall, except as provided in paragraphs (2), (3), and (4) of this subsection, make the change in accordance with the following:

''(A) Not later than 100 days after the report is submitted under subsection (e)(7)(A), the official shall initiate the applicable public process required in subsection (d) toward making the change.

''(B) The change shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

''(2) INAPPLICABILITY TO CERTAIN REORGANIZATIONS.—Paragraph (1) does not apply to a recommendation made in a report under subsection (e)(2)(A) if the recommendation is for—

''(A) an organizational change under subsection (d)(2) that constitutes the establishment, termination, or consolidation of one or more national research institutes or national centers; or

''(B) an organizational change under subsection (d)(3).

''(3) OBJECTION BY DIRECTOR OF NIH.—

''(A) IN GENERAL.—Paragraph (1) does not apply to a recommendation for an organizational change made in a report under subsection (e)(2)(A) if, not later than 90 days after the report is submitted under subsection (e)(7)(A), the Director of NIH submits to the committees specified in such subsection a report providing that the Director objects to the change, which report includes the reasons underlying the objection.

''(B) SCOPE OF OBJECTION.—For purposes of subparagraph (A), an objection by the Director of NIH may be made to the entirety of a recommended organizational change or to 1 or more aspects of the change. Any aspect of a change not objected to by the Director in a report under subparagraph (A) shall be implemented in accordance with paragraph (1).

''(4) CONGRESSIONAL REVIEW.—An organizational change under subsection (d)(2) that is initiated pursuant to paragraph (1) shall be carried out by regulation in accordance with the procedures for substantive rules under section 553 of title 5, United States Code. A rule under the preceding sentence shall be considered a major rule for purposes of chapter 8 of such title (relating to congressional review of agency rulemaking).

''(g) DEFINITIONS.—For purposes of this title:

''(1) The term 'Director of NIH' means the Director of the National Institutes of Health.

''(2) The terms 'national research institute' and 'national center' mean an agency of the National Institutes of Health that is—

''(A) listed in subsection (b) and not terminated under subsection (d)(2)(A); or

''(B) established by the Director of NIH under such subsection.

''(h) REFERENCES TO NIH.—For purposes of this title, a reference to the National Institutes of Health includes its agencies.''.

(c) CONFORMING AMENDMENTS.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) by redesignating subpart 3 of part E as subpart 19;

(2) by transferring subpart 19, as so redesignated, to part C of such title IV;

(3) by inserting subpart 19, as so redesignated, after subpart 18 of such part C; and

(4) in subpart 19, as so redesignated—

(A) by redesignating section 485B as section 464z–1;

(B) by striking ''National Center for Human Genome Research'' each place such term appears and inserting ''National Human Genome Research Institute''; and

(C) by striking ''Center'' each place such term appears and inserting ''Institute''.

SEC. 102. AUTHORITY OF DIRECTOR OF NIH.

(a) SECRETARY ACTING THROUGH THE DIRECTOR.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by redesignating paragraph (14) as paragraph (22);

(2) by striking paragraphs (12) and (13);

(3) by redesignating paragraphs (4) through (11) as paragraphs (14) through (21);

(4) in paragraph (21) (as so redesignated), by inserting ''and'' after the semicolon at the end;

(5) in the matter after and below paragraph (22) (as so redesignated), by striking ''paragraph (6)'' and inserting ''paragraph (16)''; and

(6) by striking ''the Secretary'' in the matter preceding paragraph (1) and all that follows through paragraph (1) and inserting the following: ''the Secretary, acting through the Director of NIH—

''(1) shall carry out this title, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;''.

(b) ADDITIONAL AUTHORITIES.—Section 402(b) of the Public Health Service Act, as amended by subsection (a) of this section, is amended by striking paragraphs (2) and (3) and inserting the following:

''(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

''(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

''(4) shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities;

''(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health;

''(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

''(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

''(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

''(ii) include information on such research in reports under section 403; and

''(iii) in the case of such research supported with funds referred to in subparagraph (B)—

''(I) require as appropriate that proposals include milestones and goals for the research;

''(II) require that the proposals include timeframes for funding of the research; and

''(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

''(B) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

''(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

''(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

''(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers; and

''(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

''(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

''(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

''(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487; and

''(B) may conduct and support research training—

''(i) for which fellowship support is not provided under section 487; and

''(ii) that does not consist of residency training of physicians or other health professionals;

''(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

''(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;''.

(c) CERTAIN AUTHORITIES.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by striking subsections (i) and (l); and

(2) by redesignating subsections (j) and (k) as subsections (i) and (j), respectively.

(d) ADVISORY COUNCIL FOR DIRECTOR OF NIH.—Section 402 of the Public Health Service Act, as amended by subsection (c) of this section, is amended by adding after subsection (j) the following subsection:

''(k) COUNCIL OF COUNCILS.—

''(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the 'Council of Councils' (referred to in this subsection as the 'Council') for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

''(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

''(i) the representation of a broad range of disciplines and perspectives; and

''(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

''(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who

have been nominated to serve on the Council, which list shall consist of the following:

''(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

''(I) two shall be scientists; and

''(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

''(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

''(iii) Members of the Council of Public Representatives.

''(3) TERMS.—

''(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

''(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

''(i) nine for a term of 6 years;

''(ii) nine for a term of 4 years; and

''(iii) nine for a term of 2 years.

''(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.''.

(e) REVIEW BY ADVISORY COUNCILS OF RESEARCH PROPOSALS.—Section 492A(a)(2) of the Public Health Service Act (42 U.S.C. 289a–1(a)(2)) is amended by inserting before the period the following: '', and unless a majority of the voting members of the appropriate advisory council under section 406, or as applicable, of the advisory council under section 402(k), has recommended the proposal for approval''.

(f) CONFORMING AMENDMENTS.—

(1) PUBLIC HEALTH SERVICE ACT.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(A) in section 402(a), by striking ''Director of the National Institutes of Health'' and all that follows through ''who shall'' and inserting ''Director of NIH who shall''; and

(B) in sections 405(c)(3)(A), 452(c)(1)(E)(i), and 492(a)(2), by striking the term ''402(b)(6)'' each place such term appears and inserting ''402(b)(16)''.

(2) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 561(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended in the matter following paragraph (7) by striking ''402(j)(3)'' and inserting ''402(i)(3)''.

(g) RULE OF CONSTRUCTION REGARDING AUTHORITIES OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—This Act and the amendments made by this Act may not be construed as affecting the authorities of the national research institutes and national centers that were in effect under the Public Health Service Act on the day before the date of the enactment of this Act, subject to the authorities of the Secretary of Health and Human Services and the Director of NIH under section 401 of the Public Health Service Act (as amended by section 101 of this Act). For purposes of the preceding sentence, the terms ''national research institute'', ''national center'', and ''Director of NIH'' have the meanings given such terms in such section 401.

SEC. 103. AUTHORIZATION OF APPROPRIATIONS.

(a) FUNDING.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by inserting after section 402 the following:

''SEC. 402A. AUTHORIZATION OF APPROPRIATIONS.

''(a) IN GENERAL.—For the purpose of carrying out this title, there are authorized to be appropriated—

''(1) $30,331,309,000 for fiscal year 2007;

''(2) $32,831,309,000 for fiscal year 2008; and

''(3) such sums as may be necessary for fiscal year 2009.

''(b) OFFICE OF THE DIRECTOR.—Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this title carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

''(c) TRANS-NIH RESEARCH.—

''(1) COMMON FUND.—

''(A) ACCOUNT.—For the purpose of allocations under section 402(b)(7)(B) (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

''(B) RESERVATION.—

''(i) IN GENERAL.—Of the total amount appropriated under subsection (a) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

''(ii) MINIMUM AMOUNT.—For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

''(C) COMMON FUND STRATEGIC PLANNING REPORT.—Not later than June 1, 2007, and every 2 years thereafter, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 402(b)(7)(A)(i) (including personnel needs) through the Common Fund. Each such plan shall include the following:

''(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

''(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

''(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 402(b)(7)(A)(i)—

''(I) that is in addition to the research activities described in clause (ii); and

''(II) for which there is the most substantial need.

''(D) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

''(2) TRANS-NIH RESEARCH REPORTING.—

''(A) LIMITATION.—With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

''(B) REPORTING.—Not later than January 1, 2008, and each January 1st thereafter—

''(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

''(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).

''(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 402(b)(7)(B) shall be included.

''(D) VERIFICATION OF AMOUNTS.—Upon receipt of each report submitted under subparagraph (B)(i), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

''(E) WAIVER.—At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B)(i) is inconsistent with the mission of such institute or center.

''(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a) by more than 1 percent.

''(e) RULE OF CONSTRUCTION.—This section may not be construed as affecting the authorities of the Director of NIH under section 401.''.

(b) ELIMINATION OF OTHER AUTHORIZATIONS OF APPROPRIATIONS.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) by striking the first sentence of paragraph (5) of section 402(i) (as redesignated by section 102(b));

(2) by striking subsection (e) of section 403A;

(3) by striking subsection (c) of section 404B;

(4) by striking subsection (h) of section 404E;

(5) by striking subsection (d) of section 404F;

(6) by striking subsection (e) of section 404G;

(7) by striking subsection (d) of section 409A;

(8) in section 409B—

(A) in subsection (a), by striking ''under subsection (e)'' and inserting ''to carry out this section''; and

(B) by striking subsection (e);

(9) by striking subsection (e) of section 409C;

(10) in section 409D—

(A) by striking subsection (d); and

(B) by redesignating subsection (e) as subsection (d);

(11) by striking subsection (e) of section 409E;

(12) by striking subsection (c) of section 409F;

(13) in section 409H, by striking—

(A) paragraph (3) of subsection (a);

(B) paragraph (3) of subsection (b);

(C) paragraph (5) of subsection (c); and

(D) paragraph (4) of subsection (d);

(14) by striking subsection (d) of section 409I;

(15) by striking section 417B;

(16) by striking subsection (g) of section 417C;

(17) in section 417D, by striking—

(A) paragraph (3) of subsection (a); and

(B) paragraph (3) of subsection (b);

(18) by striking subsection (d) of section 424A;

(19) by striking subsection (c) of section 424B;

(20) by striking section 425;

(21) by striking subsection (d) of section 434A;

(22) by striking subsection (d) of section 441A;

(23) by striking subsection (c) of section 442A;

(24) in section 445H—

(A) by striking subsection (b); and

(B) in subsection (a), by striking ''(a)'';

(25) by striking subsection (d) of section 445I;

(26) by striking section 445J;
(27) in section 447A—
(A) by striking subsection (b); and
(B) in subsection (a), by striking ''(a)'';
(28) by striking subsection (d) of section 447B;
(29) by striking subsection (g) in section 452A;
(30) by striking paragraph (7) in section 452E(b);
(31) in section 452G—
(A) by striking subsection (b); and
(B) in subsection (a), by striking ''(a) ENHANCED SUPPORT.—'';
(32) by striking subsection (d) of section 464H;
(33) by striking subsection (d) of section 464L;
(34) by striking paragraph (4) of section 464N(c);
(35) by striking subsection (e) of section 464P;
(36) by striking subsection (f) of section 464R;
(37) by striking subsection (d) of section 464z;
(38) in section 467—
(A) by striking the first sentence;
(B) by striking ''for such buildings and facilities'' and inserting ''for suitable and adequate buildings and facilities for use of the Library''; and
(C) by striking ''The amounts authorized to be appropriated by this section include'' and inserting ''Amounts appropriated to carry out this section may be used for'';
(39) by striking section 468;
(40) in section 481A—
(A) in the matter preceding subparagraph (A) of subsection (c)(2)—
(i) by striking the term ''under subsection (i)(1)'' and inserting ''to carry out this section''; and
(ii) by striking ''under such subsection'' and inserting ''to carry out this section''; and
(B) by striking subsection (i);
(41) in subsection (a) of section 481B, by striking ''under section 481A(h)'' and inserting ''to carry out section 481A'';
(42) by striking subsection (c) in the section 481C that relates to general clinical research centers;
(43) by striking subsection (e) in section 485C;
(44) by striking subsection (l) in section 485E;
(45) by striking subsection (h) in section 485F;
(46) by striking subsection (e) in section 485G;
(47) by striking subsection (d) of section 487;
(48) by striking subsection (c) of section 487A; and
(49) by striking subsection (c) in the section 487F that relates to a loan repayment program regarding clinical researchers.

(c) RULE OF CONSTRUCTION REGARDING CONTINUATION OF PROGRAMS.—The amendment of a program by a provision of subsection (b) may not be construed as terminating the authority of the Federal agency involved to carry out the program.

SEC. 104. REPORTS.

(a) REPORT OF DIRECTOR OF NIH.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 103(a) of this Act, is amended—
(1) by redesignating section 403A as section 403C;
(2) in section 1710(a), by striking ''section 403A'' and inserting ''section 403C''; and
(3) by striking section 403 and inserting the following sections:

''SEC. 402B. ELECTRONIC CODING OF GRANTS AND ACTIVITIES.

''The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

''SEC. 403. BIENNIAL REPORTS OF DIRECTOR OF NIH.

''(a) IN GENERAL.—The Director of NIH shall submit to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

''(1) An assessment of the state of biomedical and behavioral research.

''(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

''(3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 402(b)(7) through the Division of Program Coordination, Planning, and Strategic Initiatives.

''(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

''(A) The catalog shall, for each such activity—

''(i) identify the agency or agencies involved;

''(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

''(iii) identify whether the activity was carried out through a center of excellence.

''(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on minority health and health disparities.

''(C) Research activities listed in the catalog shall include, where applicable, the following:

''(i) Epidemiological studies and longitudinal studies.

''(ii) Disease registries, information clearinghouses, and other data systems.

''(iii) Public education and information campaigns.

''(iv) Training activities, including—

''(I) National Research Service Awards and Clinical Transformation Science Awards;

''(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in which the programs received funding under this title;

''(III) investigator-initiated awards for postdoctoral training;

''(IV) a breakdown by demographic variables and other appropriate categories; and

''(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

''(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 492B (regarding inclusion of women and minorities in clinical research).

''(vi) Translational research activities with other agencies of the Public Health Service.

''(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

''(A) Cancer.

''(B) Neurosciences.

''(C) Life stages, human development, and rehabilitation.

''(D) Organ systems.

''(E) Autoimmune diseases.

''(F) Genomics.

''(G) Molecular biology and basic science.

''(H) Technology development.

''(I) Chronic diseases, including pain and palliative care.

''(J) Infectious diseases and bioterrorism.

''(K) Minority health and health disparities.

''(L) Such additional categories as the Director determines to be appropriate.

''(6) A review of each entity receiving funding under this title in its capacity as a center of excellence (in this paragraph referred to as a 'center of excellence'), including the following:

''(A) An evaluation of the performance and research outcomes of each center of excellence.

''(B) Recommendations for promoting coordination of information among the centers of excellence.

''(C) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

''(D) If no additional centers of excellence have been funded under this title since the previous report under this section, an explanation of the reasons for not funding any additional centers.

''(b) REQUIREMENT REGARDING DISEASE-SPECIFIC RESEARCH ACTIVITIES.—In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

''(1) present information in a standardized format;

''(2) identify the actual dollar amounts obligated for such activities; and

''(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

''(c) ADDITIONAL REPORTS.—In addition to reports required by subsections (a) and (b), the Director of NIH or the head of a national research institute or national center may submit to the Congress such additional reports as the Director or the head of such institute or center determines to be appropriate.

''SEC. 403A. ANNUAL REPORTING TO INCREASE INTERAGENCY COLLABORATION AND COORDINATION.

''(a) COLLABORATION WITH OTHER HHS AGENCIES.—On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

''(b) CLINICAL TRIALS.—Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 402(i).

''(c) HUMAN TISSUE SAMPLES.—On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

''(d) FIRST REPORT.—The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

''SEC. 403B. ANNUAL REPORTING TO PREVENT FRAUD AND ABUSE.

''(a) WHISTLEBLOWER COMPLAINTS.—

''(1) IN GENERAL.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

''(2) CONTENTS.—For each whistleblower complaint pending during the year for which a report is submitted under this subsection, the report shall identify the following:

''(A) Each agency of the National Institutes of Health involved.

''(B) The status of the complaint.

''(C) The resolution of the complaint to date.

''(b) EXPERTS AND CONSULTANTS.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report that—

''(1) identifies the number of experts and consultants, including any special consultants, whose services are obtained by the National Institutes of Health or its agencies;

''(2) specifies whether such services were obtained under section 207(f), section 402(d), or other authority;

''(3) describes the qualifications of such experts and consultants;

''(4) describes the need for hiring such experts and consultants; and

''(5) if such experts and consultants make financial disclosures to the National Institutes of Health or any of its agencies, specifies the income, gifts, assets, and liabilities so disclosed.

''(c) FIRST REPORT.—The first report under subsections (a) and (b) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

''SEC. 403C. ANNUAL REPORTING REGARDING TRAINING OF GRADUATE STUDENTS FOR DOCTORAL DEGREES.

''(a) IN GENERAL.—Each institution receiving an award under this title for the training of graduate students for doctoral degrees shall annually report to the Director of NIH, with respect to each degree-granting program at such institution—

''(1) the percentage of students admitted for study who successfully attain a doctoral degree; and

''(2) for students described in paragraph (1), the average time between the beginning of graduate study and the receipt of a doctoral degree.

''(3) PROVISION OF INFORMATION TO APPLICANTS.—Each institution described in subsection (a) shall provide to each student submitting an application for a program of graduate study at such institution the information described in paragraphs (1) and (2) of such subsection with respect to the program or programs to which such student has applied.''.

(b) STRIKING OF OTHER REPORTING REQUIREMENTS FOR NIH.—

(1) PUBLIC HEALTH SERVICE ACT; TITLE IV.—Title IV of the Public Health Service Act, as amended by section 103(b) of this Act, is amended—

(A) in section 404E(b)—

(i) by amending paragraph (3) to read as follows:

''(3) COORDINATION OF CENTERS.—The Director of NIH shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers.''; and

(ii) by striking subsection (f) and redesignating subsection (g) as subsection (f);

(B) in section 404F(b)(1), by striking subparagraphs (F) and (G);

(C) by striking section 407;

(D) in section 409C(b), by striking paragraph (4) and redesignating paragraphs (5) and (6) as paragraphs (4) and (5), respectively;

(E) in section 409E, by striking subsection (d);

(F) in section 417C, by striking subsection (f);

(G) in section 424B(a)—

(i) in paragraph (1), by adding ''and'' after the semicolon at the end;

(ii) in paragraph (2), by striking ''; and'' and inserting a period; and

(iii) by striking paragraph (3);

(H) in section 429, by striking subsections (c) and (d);

(I) in section 442, by striking subsection (j) and redesignating subsection (k) as subsection (j);

(J) in section 464D, by striking subsection (j);

(K) in section 464E, by striking subsection (e);

(L) in section 464T, by striking subsection (e);

(M) in section 481A, by striking subsection (h);

(N) in section 485E, by striking subsection (k);

(O) in section 485H—

(i) by striking ''(a)'' and all that follows through ''The Secretary,'' and inserting ''The Secretary,''; and

(ii) by striking subsection (b); and

(P) in section 494—

(i) by striking ''(a) If the Secretary'' and inserting ''If the Secretary''; and

(ii) by striking subsection (b).

(2) PUBLIC HEALTH SERVICE ACT; OTHER PROVISIONS.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(A) in section 399E, by striking subsection (e);

(B) in section 1122—

(i) by striking ''(a) From the sums'' and inserting ''From the sums''; and

(ii) by striking subsections (b) and (c);

(C) by striking section 2301;

(D) in section 2354, by striking subsection (b) and redesignating subsection (c) as subsection (b);

(E) in section 2356, by striking subsection (e) and redesignating subsections (f) and (g) as subsections (e) and (f), respectively; and

(F) in section 2359(b)—

(i) by striking paragraph (2);

(ii) by striking ''(b) EVALUATION AND REPORT'' and all that follows through ''Not later than 5 years'' and inserting ''(b) EVALUATION.—Not later than 5 years'';

(iii) by redesignating subparagraphs (A) through (C) as paragraphs (1) through (3), respectively; and

(iv) by moving each of paragraphs (1) through (3) (as so redesignated) 2 ems to the left.

(3) OTHER ACTS.—Provisions of Federal law are amended as follows:

(A) Section 7 of Public Law 97–414 is amended—

(i) in subsection (a)—

(I) in paragraph (2), by inserting ''and'' at the end;

(II) in paragraph (3), by striking ''; and'' and inserting a period; and

(III) by striking paragraph (4); and

(ii) in subsection (b), by striking the last sentence of paragraph (3).

(B) Title III of Public Law 101–557 (42 U.S.C. 242q et seq.) is amended by striking section 304 and redesignating section 305 and 306 as sections 304 and 305, respectively.

(C) Section 4923 of Public Law 105–33 is amended by striking subsection (b).

(D) Public Law 106–310 is amended by striking section 105.

(E) Section 1004 of Public Law 106–310 is amended by striking subsection (d).

(F) Section 3633 of Public Law 106–310 (as amended by section 2502 of Public Law 107–273) is repealed.

(G) Public Law 106–525 is amended by striking section 105.

(H) Public Law 107–84 is amended by striking section 6.

(I) Public Law 108–427 is amended by striking section 3 and redesignating sections 4 and 5 as sections 3 and 4, respectively.

SEC. 105. CERTAIN DEMONSTRATION PROJECTS.

(a) BRIDGING THE SCIENCES.—

(1) IN GENERAL.—From amounts to be appropriated under section 402A(b) of the Public Health Service Act, the Secretary of Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the ''Secretary'') in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

(2) GOALS, PRIORITIES, AND METHODS; INTERAGENCY COLLABORATION.—The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that—

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

(3) PEER REVIEW.—A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 492 of the Public Health Service Act (42 U.S.C. 289a) and has been reviewed by the advisory council under section 402(k) of such Act (as added by section 102(c) of this Act) or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

(b) HIGH-RISK, HIGH-REWARD RESEARCH.—

(1) IN GENERAL.—From amounts to be appropriated under section 402A(b) of the Public Health Service Act, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and national centers to make awards of grants or contracts or to engage in other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

(2) SPECIAL CONSIDERATION.—In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

(3) ADMINISTRATION OF PROGRAM.—Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

(4) PUBLIC-PRIVATE PARTNERSHIPS.—In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partnerships between public and private entities and shall coordinate when appropriate with the Foundation for the National Institutes of Health.

(5) PEER REVIEW.—A grant for research described in paragraph (1) may be made only if the application for the grant has undergone technical and scientific peer review under section 492 of the Public Health Service Act (42 U.S.C. 289a) and has been reviewed by the advisory council under section 402(k) of such Act (as added by section 102(c) of this Act).

(c) REPORT TO CONGRESS.—Not later than the end of fiscal year 2009, the Secretary, acting through the Director of NIH, shall conduct an evaluation of the activities under this section and submit a report to the Congress on the results of such evaluation.

(d) DEFINITIONS.—For purposes of this section, the terms ''Director of NIH'' , ''national research institute'', and ''national center'' have the meanings given such terms in section 401 of the Public Health Service Act.

SEC. 106. ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD.

(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act, the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

(c) DEFINITION.—For purposes of this section, the term ''Director of NIH'' has the meaning given such term in section 401 of the Public Health Service Act.

SEC. 107. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

Section 499 of the Public Health Service Act (42 U.S.C. 290b) is amended—

(1) in subsection (d)—

(A) in paragraph (1)—

(i) by amending subparagraph (D)(ii) to read as follows:

''(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.''; and

(ii) in subparagraph (G), by inserting ''appointed'' after ''that the number of'';

(B) by amending paragraph (3)(B) to read as follows:

''(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.''; and

(C) in paragraph (5), by inserting ''appointed'' after ''majority of the'';

(2) in subsection (j)—

(A) in paragraph (2), by striking ''(d)(2)(B)(i)(II)'' and inserting ''(d)(6)'';

(B) in paragraph (4)—

(i) in subparagraph (A), by inserting '', including an accounting of the use of amounts transferred under subsection (l)'' before the period at the end; and

(ii) by striking subparagraph (C) and inserting the following:

''(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

''(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

''(ii) to the appropriate committees of Congress.''; and

(C) in paragraph (10), by striking ''of Health.'' and inserting ''of Health and the National Institutes of Health may accept transfers of funds from the Foundation.''; and

(3) by striking subsection (l) and inserting the following:

''(l) FUNDING.—From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer not less than $500,000 and not more than $1,250,000 to the Foundation.''.

SEC. 108. MISCELLANEOUS AMENDMENTS.

(a) CERTAIN AUTHORITIES OF THE SECRETARY.—

(1) IN GENERAL.—Section 401 of the Public Health Service Act, as added and amended by section 101, is amended in subsection (d) by inserting after paragraph (1) a subsection that is identical to section 401(c) of such Act as in effect on the day before the date of the enactment of this Act. The subsection so inserted is amended—

(A) by striking ''(c)(1) The Secretary may'' and inserting the following:

''(2) REORGANIZATION OF INSTITUTES.—

''(A) IN GENERAL.—The Secretary may'';

(B) by striking ''(A) the Secretary determines'' and inserting the following:

''(i) the Secretary determines'';

(C) by striking ''(B) the additional'' and inserting the following:

''(ii) the additional''; and

(D) by striking ''(2) The Secretary may'' and inserting the following:

''(B) ADDITIONAL AUTHORITY.—The Secretary may''.

(2) CONFORMING AMENDMENTS.—Section 401(d)(2) of the Public Health Service Act, as designated by paragraph (1) of this subsection, is amended—

(A) in subparagraph (A)(ii), by striking ''subparagraph (A)'' and inserting ''clause (i)''; and

(B) by striking ''Labor and Human Resources'' each place such term appears and inserting ''Health, Education, Labor, and Pensions''.

(b) CERTAIN RESEARCH CENTERS.—Section 414 of the Public Health Service Act (42 U.S.C. 285a–3) is amended by adding at the end the following subsection:

''(d) Research centers under this section may not be considered centers of excellence for purposes of section 402(b)(10).''.

SEC. 109. APPLICABILITY.

This title and the amendments made by this title apply only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years.

TITLE II—MISCELLANEOUS PROVISIONS

SEC. 201. REDISTRIBUTION OF CERTAIN UNUSED SCHIP ALLOTMENTS FOR FISCAL YEARS 2004 AND 2005 TO REDUCE FUNDING SHORTFALLS FOR FISCAL YEAR 2007.

(a) REDISTRIBUTION OF CERTAIN UNUSED SCHIP ALLOTMENTS.—Section 2104 of the Social Security Act (42 U.S.C. 1397dd) is amended by adding at the end the following new subsection:

''(h) SPECIAL RULES TO ADDRESS FISCAL YEAR 2007 SHORTFALLS.—

''(1) REDISTRIBUTION OF UNUSED FISCAL YEAR 2004 ALLOTMENTS.—

''(A) IN GENERAL.—Notwithstanding subsection (f) and subject to subparagraphs (C) and (D), with respect to months beginning during fiscal year 2007, the Secretary shall provide for a redistribution under such subsection from the allotments for fiscal year 2004 under subsection (b) that are not expended by the end of fiscal year 2006, to a shortfall State described in subparagraph (B), such amount as the Secretary determines will eliminate the estimated shortfall described in such subparagraph for such State for the month.

''(B) SHORTFALL STATE DESCRIBED.—For purposes of this paragraph, a shortfall State described in this subparagraph is a State with a State child health plan approved under this title for which the Secretary estimates, subject to paragraph (4)(B) and on a monthly basis using the most recent data available to the Secretary as of such month, that the projected expenditures under such plan for such State for fiscal year 2007 will exceed the sum of—

''(i) the amount of the State's allotments for each of fiscal years 2005 and 2006 that was not expended by the end of fiscal year 2006; and

''(ii) the amount of the State's allotment for fiscal year 2007.

''(C) FUNDS REDISTRIBUTED IN THE ORDER IN WHICH STATES REALIZE FUNDING SHORTFALLS.—The Secretary shall redistribute the amounts available for redistribution under subparagraph (A) to shortfall States described in subparagraph (B) in the order in which such States realize monthly funding shortfalls under this title for fiscal year 2007. The Secretary shall only make redistributions under this paragraph to the extent that there are unexpended fiscal year 2004 allotments under subsection (b) available for such redistributions.

''(D) PRORATION RULE.—If the amounts available for redistribution under subparagraph (A) for a month are less than the total amounts of the estimated shortfalls determined for the month under that subparagraph, the amount computed under such subparagraph for each shortfall State shall be reduced proportionally.

''(2) FUNDING REMAINDER OF REDUCTION OF SHORTFALL FOR FISCAL YEAR 2007 THROUGH REDISTRIBUTION OF CERTAIN UNUSED FISCAL YEAR 2005 ALLOTMENTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D) and paragraph (5)(B), with respect to months beginning during fiscal year 2007 after March 31, 2007, the Secretary shall provide for a redistribution under subsection (f) from amounts made available for redistribution under paragraph (3) to each shortfall State described in subparagraph (B), such amount as the Secretary determines will eliminate the estimated shortfall described in such subparagraph for such State for the month.

''(B) SHORTFALL STATE DESCRIBED.—For purposes of this paragraph, a shortfall State described in this subparagraph is a State with a State child health plan approved under this title for which the Secretary estimates, subject to paragraph (4)(B) and on a monthly basis using the most recent data available to the Secretary as of March 31, 2007, that the projected expenditures under such plan for such State for fiscal year 2007 will exceed the sum of—

''(i) the amount of the State's allotments for each of fiscal years 2005 and 2006 that was not expended by the end of fiscal year 2006;

''(ii) the amount, if any, that is to be redistributed to the State in accordance with paragraph (1); and

''(iii) the amount of the State's allotment for fiscal year 2007.

''(C) FUNDS REDISTRIBUTED IN THE ORDER IN WHICH STATES REALIZE FUNDING SHORTFALLS.—The Secretary shall redistribute the amounts available for redistribution under subparagraph (A) to shortfall States described in subparagraph (B) in the order in which such States realize monthly funding shortfalls under this title for fiscal year 2007. The Secretary shall only make redistributions under this paragraph to the extent that such amounts are available for such redistributions.

''(D) PRORATION RULE.—If the amounts available for redistribution under paragraph (3) for a month are less than the total amounts of the estimated shortfalls determined for the month under subparagraph (A), the amount computed under such subparagraph for each shortfall State shall be reduced proportionally.

''(3) TREATMENT OF CERTAIN STATES WITH FISCAL YEAR 2005 ALLOTMENTS UNEXPENDED AT THE END OF THE FIRST HALF OF FISCAL YEAR 2007.—

''(A) IDENTIFICATION OF STATES.—The Secretary, on the basis of the most recent data available to the Secretary as of March 31, 2007—

''(i) shall identify those States that received an allotment for fiscal year 2005 under subsection (b) which have not expended all of such allotment by March 31, 2007; and

''(ii) for each such State shall estimate—

''(I) the portion of such allotment that was not so expended by such date; and

''(II) whether the State is described in subparagraph (B).

''(B) STATES WITH FUNDS IN EXCESS OF 200 PERCENT OF NEED.—A State described in this subparagraph is a State for which the Secretary determines, on the basis of the most recent data

available to the Secretary as of March 31, 2007, that the total of all available allotments under this title to the State as of such date, is at least equal to 200 percent of the total projected expenditures under this title for the State for fiscal year 2007.

''(C) REDISTRIBUTION AND LIMITATION ON AVAILABILITY OF PORTION OF UNUSED ALLOTMENTS FOR CERTAIN STATES.—

''(i) IN GENERAL.—In the case of a State identified under subparagraph (A)(i) that is also described in subparagraph (B), notwithstanding subsection (e), the applicable amount described in clause (ii) shall not be available for expenditure by the State on or after April 1, 2007, and shall be redistributed in accordance with paragraph (2).

''(ii) APPLICABLE AMOUNT.—For purposes of clause (i), the applicable amount described in this clause is the lesser of—

''(I) 50 percent of the amount described in subparagraph (A)(ii)(I); or

''(II) $20,000,000.

''(4) SPECIAL RULES.—

''(A) EXPENDITURES LIMITED TO COVERAGE FOR POPULATIONS ELIGIBLE ON OCTOBER 1, 2006.—A State shall use amounts redistributed under this subsection only for expenditures for providing child health assistance or other health benefits coverage for populations eligible for such assistance or benefits under the State child health plan (including under a waiver of such plan) on October 1, 2006.

''(B) REGULAR FMAP FOR EXPENDITURES FOR COVERAGE OF NONCHILD POPULATIONS.—To the extent a State uses amounts redistributed under this subsection for expenditures for providing child health assistance or other health benefits coverage to an individual who is not a child or a pregnant woman, the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) applicable to the State for the fiscal year shall apply to such expenditures for purposes of making payments to the State under subsection (a) of section 2105 from such amounts.

''(5) RETROSPECTIVE ADJUSTMENT.—

''(A) IN GENERAL.—The Secretary may adjust the estimates and determinations made under paragraphs (1), (2), and (3) as necessary on the basis of the amounts reported by States not later than November 30, 2007, on CMS Form 64 or CMS Form 21, as the case may be and as approved by the Secretary, but in no case may the applicable amount described in paragraph (3)(C)(ii) exceed the amount determined by the Secretary on the basis of the most recent data available to the Secretary as of March 31, 2007.

''(B) FUNDING OF ANY RETROSPECTIVE ADJUSTMENTS ONLY FROM UNEXPENDED 2005 ALLOTMENTS.—Notwithstanding subsections (e) and (f), to the extent the Secretary determines it necessary to adjust the estimates and determinations made for purposes of paragraphs (1), (2), and (3), the Secretary may use only the allotments for fiscal year 2005 under subsection (b) that remain unexpended through the end of fiscal year 2007 for providing any additional amounts to States described in paragraph (2)(B) (without regard to whether such unexpended allotments are from States described paragraph (3)(B)).

''(C) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(i) authorizing the Secretary to use the allotments for fiscal year 2006 or 2007 under subsection (b) of States described in paragraph (3)(B) to provide additional amounts to States described in paragraph (2)(B) for purposes of eliminating the funding shortfall for such States for fiscal year 2007; or

''(ii) limiting the authority of the Secretary to redistribute the allotments for fiscal year 2005 under subsection (b) that remain unexpended through the end of fiscal year 2007 and are available for redistribution under subsection (f) after the application of subparagraph (B).

''(6) 1-YEAR AVAILABILITY; NO FURTHER REDISTRIBUTION.—Notwithstanding subsections (e) and (f), amounts redistributed to a State pursuant to this subsection for fiscal year 2007 shall only remain available for expenditure by the State through September 30, 2007, and any amounts of such redistributions that remain unexpended as of such date, shall not be subject to redistribution under subsection (f). Nothing in the preceding sentence shall be construed as limiting the ability of the Secretary to adjust the determinations made under paragraphs (1), (2), and (3) in accordance with paragraph (5).

''(7) DEFINITION OF STATE.—For purposes of this subsection, the term 'State' means a State that receives an allotment for fiscal year 2007 under subsection (b).''.

(b) EXTENDING AUTHORITY FOR QUALIFYING STATES TO USE CERTAIN FUNDS FOR MEDICAID EXPENDITURES.—Section 2105(g)(1)(A) of such Act (42 U.S.C. 1397ee(g)(1)(A)) is amended by striking ''or 2005'' and inserting ''2005, 2006, or 2007''.

(c) REPORT TO CONGRESS.—Not later than April 30, 2007, the Secretary of Health and Human Services shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate regarding the amounts redistributed to States under section 2104 of the Social Security Act to reduce funding shortfalls for the State Children's Health Insurance Program (SCHIP) for fiscal year 2007. Such report shall include descriptions and analyses of—

(1) the extent to which such redistributed amounts have reduced or eliminated such shortfalls on the basis of reports by States submitted to the Secretary as of April 1, 2007; and

(2) the effect of the redistribution and limited availability of unexpended fiscal year 2005 allotments under such program on the States described in section 2104(h)(3)(B) of the Social Security Act (42 U.S.C. 1397dd(h)(3)(B)) on the basis of reports by States submitted to the Secretary as of such date.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BARTON) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Texas.

Mr. BARTON of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in the absolute strongest possible support of passage of the National Institutes of Health Reauthorization Act. This legislation, as amended by the Senate, passed the House by landmark votes several months ago of 414–2. It is not often that we see a bill of this magnitude receive such widespread support in both the House and the Senate.

We should all be proud of ourselves for this bipartisan, bicameral product. This represents the culmination of three hard-fought years spent trying to reauthorize the NIH, a crown jewel of the Federal Government.

When I first took over as chairman of the Energy and Commerce Committee, I was surprised to learn that such an important agency of our Federal Government had not been authorized for over 13 years. Now I know why. The amount of work required to restructure this agency and at the same time gain the involvement and support of all the stakeholders and advocacy groups has been absolutely breathtaking.

However, having said that, the hard work has paid off, and we now see the fruits of our labors before us this evening. The Energy and Commerce Committee has adopted numerous pieces of legislation in the years that I have served as chairman, but I would not put one piece of legislation, including the Energy Policy Act, which was a very major effort, above the importance of this bill that is before us right now.

I want to thank Congressman JOHN DINGELL, the ranking member, soon to be the chairman again of the committee, for his tireless efforts.

I want to thank ANNA ESHOO. I want to thank RICHARD NEAL. I want to thank the Speaker of the House, and the majority leader, JOHN BOEHNER. I want to thank BILL FRIST, thank HARRY REID, I want to thank TED KENNEDY. I want to thank Mr. GRASSLEY, I want to thank Mr. LOTT, Mr. HARKIN. I could go on and on for all the Senators and House Members who have worked to make this legislation possible.

It is truly a bipartisan effort, and a major, major accomplishment of this Congress. I also want to thank the current director at the NIH, Dr. Elias Zerhouni. He has been absolutely astounding in his continual optimistic efforts to approve this bill and to gain support for it.

I want to thank all the stakeholders, over 90 national organizations have endorsed this legislation. I want to thank the major research universities of America for their hard work. I want to thank the 27 institute directors for their hard work.

In conclusion, I ask in the possible strongest terms for the support of every Member of this House to pass H.R. 6164, as amended by the Senate.

Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

I want to thank you, Mr. Speaker, and I want to thank Mr. BARTON and Mr. DINGELL for all their hard work on this NIH bill. As was mentioned, this is the first time in 13 years that we have had a reauthorization of the National Institutes of Health. This is an important piece of legislation because the National Institutes of Health are the world's premier research medical center and the key focal point for medical research in the United States.

On September 26, the House overwhelmingly passed H.R. 6164 with a vote of 414–2. The Senate recently passed that bill with amendments, which is the bill before us now. Those amendments helped clarify provisions in the bill and therefore improve it. So every Member who voted for H.R. 6164 on September 26 should feel comfortable voting for this bill this evening.

I wanted to mention that the bill before us also includes provisions with regard to the SCHIP, or the State Children's Health Insurance Program.

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This is another reason we should be supporting the legislation this evening.

This part of the legislation would provide the money necessary to help a number of States, including my own, avert a funding shortfall in their State Children's Health Insurance Program.

Specifically, the bill will redirect existing unspent SCHIP funds from fiscal years 2004 and 2005 to help States that will not have sufficient funds to maintain their existing programs. States forfeiting unspent funding will be held harmless by capping the amount of funds that will be donated to $20 million. Thanks to this compromise, we can prevent many States from having to limit eligibility, increase cost-sharing requirements or restrict benefits. Keeping these programs intact is critically important for the health and well-being of our Nation's children.

Since its inception, SCHIP has been an integral part of reducing the number of uninsured children. But last year, for the first time since 1998, the number of uninsured children in the country actually increased, and even more children will go without coverage if Congress does not act tonight to avoid the funding shortfall currently projected for next year.

Again, I would like thank my colleagues Mr. DINGELL and Mr. BARTON, as well as their staffs, who helped work out this compromise, as well as our Senate counterparts. Thanks to our efforts, we will help preserve access to health care coverage for millions of low income children, as well as their families.

Finally, Mr. Speaker, while we have temporarily prevented a cut to the SCHIP program tonight, we must not forget that there are still approximately 8 million American children who currently have no health insurance, many of which are eligible to participate in SCHIP. Reauthorization of the SCHIP program must be addressed early next year and we must work together to help expand coverage and increase participation. Failure to do so will undoubtedly jeopardize the health of those most vulnerable in our Nation, our children.

I would like to thank everyone again.

Mr. Speaker, I yield back the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I urge that we pass this bill unanimously, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. LAHOOD). The question is on the motion offered by the gentleman from Texas (Mr. BARTON) that the House suspend the rules and concur in the Senate amendment to the bill, H.R. 6164.

The question was taken; and (two-thirds of those voting having responded in the affirmative) the rules were suspended and the Senate amendment was concurred in.

A motion to reconsider was laid on the table.

DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT

Mr. BARTON of Texas. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 3546) to amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

The Clerk read as follows:

S. 3546

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dietary Supplement and Nonprescription Drug Consumer Protection Act''.

SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter H—Serious Adverse Event Reports

''SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including—

''(A) an event occurring from an overdose of the drug, whether accidental or intentional;

''(B) an event occurring from abuse of the drug;

''(C) an event occurring from withdrawal from the drug; and

''(D) any failure of expected pharmacological action of the drug.

''(2) NONPRESCRIPTION DRUG.—The term 'nonprescription drug' means a drug that is—

''(A) not subject to section 503(b); and

''(B) not subject to approval in an application submitted under section 505.

''(3) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' is an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant disability or incapacity; or

''(v) a congenital anomaly or birth defect; or

''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

''(4) SERIOUS ADVERSE EVENT REPORT.—The term 'serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

''(b) REPORTING REQUIREMENT.—

''(1) IN GENERAL.—The manufacturer, packer, or distributor whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

''(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such drug that are reported to the retailer through the address or telephone number described in section 502(x).

''(c) SUBMISSION OF REPORTS.—

''(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 502(x).

''(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

''(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

''(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

''(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

''(e) MAINTENANCE AND INSPECTION OF RECORDS.—

''(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

''(2) RECORDS INSPECTION.—

''(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be maintained under this section, during an inspection pursuant to section 704.

''(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services who has—

''(i) appropriate credentials, as determined by the Secretary; and

''(ii) been duly designated by the Secretary to have access to the records required under this section.

''(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

''(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

''(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.